Roche

SEP 2 1 2011

K101299

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-2110
Contact Person: Mike Flis
Date Prepared: August 03, 2011

2) Device name

Proprietary name:

ACCU-CHEK® Aviva Plus Blood Glucose Monitoring System
Meter: ACCU-CHEK Aviva Meter
Test Strip: ACCU-CHEK Aviva Plus Test Strip
Controls: ACCU-CHEK Aviva Control Solutions

Classification name: Glucose dehydrogenase, glucose test system (21 C.F.R. § 862.1345)

NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase

3) Predicate device

ACCU-CHEK Aviva System (K060620 and K043474)

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510(k) Summary, Continued

4) Device Description

The modified test strip is a blood glucose testing product used in conjunction with the ACCU-CHEK® Aviva meter.

Through the use of molecular-cloning techniques, Roche has modified the GDH enzyme to improve specificity for glucose; the modified reaction is referred to hereafter as Mut. Q-GDH.

The newly advanced test strip measures blood glucose rapidly and reliably via an electrochemical detection technique. The new version of the test strip employs a disposable dry reagent based on the Mut. Q-GDH method for glucose determination.

When a drop of blood is applied to the test strip, modified glucose dehydrogenase catalyzes the oxidation of glucose. During the reaction, electrons are transferred via the coenzyme PQQ and an electrochemical mediator to the surface of the electrode. Current generated by the reaction is proportional to the concentration of glucose present in the blood sample.

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510(k) Summary, Continued

5) Intended use

The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The ACCU-CHEK Aviva Plus Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The ACCU-CHEK Aviva Plus Test Strips are for use with the ACCU-CHEK Aviva Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, or palm.

The single-patient use ACCU-CHEK Aviva Blood Glucose Monitoring System will consist of:

Meter: ACCU-CHEK Aviva Meter
Test Strip: ACCU-CHEK Aviva Plus Test Strip
Controls: ACCU-CHEK Aviva Control Solutions

6) Substantial equivalence

The modified ACCU-CHEK Aviva Plus Test System is substantially equivalent to the ACCU-CHEK Aviva System (K060620 and K043474).

7) Data demonstrating substantial equivalence

Performance testing on the ACCU-CHEK Aviva System demonstrated that the device meets the performance requirements for its intended use. The data demonstrates that the test strip is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 21 2011

Roche Diagnostics
c/o Mike Flis
Regulatory Affairs Program Manager
9115 Hague Road
Indianapolis, IN, 46250-0457

Re: k101299
Trade Name: ACCU-CHEK Aviva Plus Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System.
Regulatory Class: Class II
Product Codes: NBW, LFR, JJX
Dated: September 16, 2011
Received: September 19, 2011

Dear Mr. Flis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): k101299
Device Name: ACCU-CHEK Aviva Plus Blood Glucose Monitoring System

Indications for Use:

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Prescription Use _____ AND Over-The-Counter Use __XX___
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K101299